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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/614,648

07/07/2003

John K. Fraser

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EXAMINER

LANKFORD JR, LEON B

ART UNIT

PAPER NUMBER

1651

NOTIFICATION DATE

DELIVERY MODE

01/07/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/614,648	Applicant(s) FRASER ET AL.	
	Examiner Leon B. Lankford	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 128-143 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 128-143 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/7/9</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's arguments filed 8/7/9 have been fully considered but they are not persuasive. The rejections remain for the reasons of record set forth in the previous office action. The evidence presented regarding applicant's Celution product is impressive however it is not commensurate in scope with the claimed invention. A showing to overcome a prima facie case of obviousness must be clear and convincing(In re Lohr et al. 137 USPQ 548) as well as commensurate in scope with the claimed subject matter (In re Lindner 173 USPQ 356; In re Hyson, 172 USPQ 399 and In re Boesch et al., 205 USPQ 215 (CCPA 1980).

Note that the limitations used to distinguish over the art have been rejected below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 128-143 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has introduced new limitations to distinguish the claimed invention over the prior art however those limitations fail to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

It is unclear what level of disaggregation is required for "substantially disaggregated." It is unclear what the metes and bounds of "prolonged survival"-

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prolonged as relative to what? What degree of survival would be considered prolonged? Also it is unclear as compared to what or to what degree applicant's invention provides "improved vascularity."

The above limitations are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 128-143 are rejected under 35 U.S.C. 102(e) as being anticipated by Katz et al (6777231).

Katz et al teach adipose tissue which contains adipose derived stem cells.

The amount of added cells required is nearly negligible (particularly in claim 93) and even where higher amounts are claimed, the resultant mixture would still seem to read

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on a typical adipose tissue sample in that the amount of cells present in the samples are not taught to be consistent and a “concentrate” mixture produced by applicant’s method will likely contain the same amount of adipose-derived cells as another mixture which is simply naturally more concentrated with the designated cells. Applicant has previously pointed out that certain adipose tissue is known to have a more naturally high concentration of the cells than others and as such the claimed invention fails to distinguish over the prior art.

Claims 128-143 are rejected under 35 U.S.C. 102(b) as being anticipated by Hu et al (5744360).

Hu et al teach adipose tissue which has been excised from the body. The tissue inherently contains adipose derived stem cells. The reference anticipates the claim subject matter. The amount of added cells required is nearly negligible (particularly in claim 93) and even where higher amounts are claimed, the resultant mixture would still seem to read on a typical adipose tissue sample in that the amount of cells present in the samples are not taught to be consistent and a “concentrate” mixture produced by applicant’s method will likely contain the same amount of adipose-derived cells as another mixture which is simply naturally more concentrated with the designated cells. Applicant has previously pointed out that certain adipose tissue is known to have a more naturally high concentration of the cells than others and as such the claimed invention fails to distinguish over the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 128-143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al(6777231) or Peterson et al(6200606).

Katz teaches compositions comprising adipose-derived stem cells in a complex mixture and substantially free of other cells and tissues. Peterson teaches compositions comprising adipose-derived stem cells in a complex mixture and substantially free of other cells and tissues. The references clearly teach how and why to purify the desired cells detailed the useful methods and means.

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Applicant's arguments have been considered but are not persuasive to overcome the rejections of record. Any difference in the claimed compositions and those taught by the prior art would be only a matter of the concentration of the cells and tissues contained therein. Generally, differences in concentration of the different cell types in the mixture will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical.

Note that MPEP § 706.3(e) states that:

"[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972) ; *In re Fessmann*, 180 USPQ 324 (CCPA1974)."

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Applicant claims a mixture of unprocessed adipose tissue mixed with disaggregated adipose derived stem cells. However, it is unclear that the resultant mixture would differ from a typical adipose tissue sample in that the cells would no longer be disaggregated after mixing with the tissue. As the resultant product by process would not appear to be different from a typical adipose tissue sample, the below rejections result. Further, though it is understood that applicant intends to claim a

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mixture wherein the amount of adipose derived stem cells is concentrated, the instant claims do not serve that purpose. The amount of added cells required is nearly negligible (particularly in claim 93) and even where higher amounts are claimed, the resultant mixture would still seem to read on a typical adipose tissue sample in that the amount of cells present in the samples are not taught to be consistent and a “concentrate” mixture produced by applicant’s method will likely contain the same amount of adipose-derived cells as another mixture which is simply naturally more concentrated with the designated cells. Applicant has previously pointed out that certain adipose tissue is known to have a more naturally high concentration of the cells than others and as such the claimed invention fails to distinguish over the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Leon B Lankford/
Primary Examiner, Art Unit 1651